MDS – G014

Guidance on Content of Labeling of Contact Lenses and its Solutions

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"Translated Copy"

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Introduction

Purpose

The purpose of this document is to define and clarify the contents of the labeling of contact lenses and its solutions that shall be provided within MDMA application.

Scope

This document is applicable to manufacturers and ARs of contact lenses and its solutions that will be making available with the KSA.

Background

SFDA/MDS has issued this document in reference to:

- Article Seventeen of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H.
- Article (10/28) of "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H
- “Requirements for Medical Devices Marketing Authorization (MDS-REQ1)”.
- Saudi standard “Ophthalmic optics – Contact lenses and contact lenses care products – Labeling (SFDA.MD/GSO ISO 11978:2019)”.

Content of Labeling of Contact Lenses and its Solutions

The labeling of contact lenses and its solutions shall be:

A. Written in English,

B. Written in Arabic (when the product is intended for a lay person) as follows:

- IFUs of the contact lenses and its solutions (completely and clearly)
- Label on the contact lens solutions
- Label on the contact lenses (at least the purpose of lenses, type of lenses, schedule for wear and replacement frequency)

Note: The transled labeling shall be approved by the manufacturer, and included in the product technical documentation available to it.

C. Containing the following information:

	Content of labeling	Soft Contact Lens		Contact Lens Solution	
		Label	IFU	Label	IFU
1.	Indication of the purpose of contact lenses (e.g. correction, cosmetic…etc)	✓	✓		
2.	Indication of the purpose of solution (e.g. rinse, clean, disinfect, store, or multipurpose ...etc.)			✓	✓
3.	Indication of contact lenses type (soft or hard)	✓	✓		
4.	Indication of schedule for wear (e.g. weekly, monthly, quarterly/three months) as applicable	✓	✓		
5.	Indication of nature of lens use (daily use and/or extended use), when applicable	✓	✓		
6.	Indication of replacement frequency (e.g. daily disposable) as applicable	✓	✓		
7.	Indication of materials properties of the contact lenses/solution	✓	✓	✓	✓
8.	Information on contact lenses parameters: contact lenses power/sphere, base curve, diameter, in addition to cylinder and axis for astigmatism , and additional spherical power for presbyopia, if applicable	✓			
9.	Indication of the statement “custom-made device”, if applicable	✓	✓	✓	✓
10.	Indication if that the product is single use, if applicable	✓	✓		
11.	Name of product (trade Name/brand Name) in English, and in Arabic as it is pronounced in English	✓	✓	✓	✓
12.	Model and/or ID of the product	✓		✓	

13.	Name and address of the manufacturer	✓	✓	✓	✓
14.	Place an indication of traceability method	✓		✓	
15.	Indication of expiry date	✓		✓	
16.	Indication of maximum period of use after the container has first been opened, if applicable			✓	
17.	Information on IF, cleaning, if applicable		✓		✓
18.	Information on any caution, precaution and warnings, and contraindications		✓		✓
19.	Information on circumstances when a lay person should consult with a healthcare professional, if applicable		✓		✓
20.	Any special storage and transportation conditions of the product.	✓	✓	✓	✓
21.	Information about sterilization method	✓	✓	✓	✓
22.	Physical appearance details (optional)	✓	✓	✓	✓
23.	Presence of machine-readable forms, such as radio-frequency identification (RFID) or bar codes	✓		✓	

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia.
SFDA	Saudi Food and Drug Authority.
Medical Device	Any instrument, apparatus, implement, implant device, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices and supplies; providing information for medical or personal purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Medical Supply	A medical substance or product used in diagnosis, treatment, prosthetics, or orthotics; or in disability cases or other medical uses for humans, including medical gases.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Authorised Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulations.
Circulation of Medical Devices and Supplies	The provision of medical devices and supplies at no cost or for a fee, whether for distribution or use.
Medical Devices Marketing Authorization (MDMA)	Marketing Authorization: A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Standard Specifications	Non-mandatory documents approved by the SFDA, including rules, guidelines, specifications of medical devices and supplies, or production processes and methods related thereto as well as terms and symbols, and packaging and labelling requirements.
Labeling/Identifying Information	Any statement, information, or illustration printed on a medical device or supply, including identifying information, technical description, method of use, and manner of storage and transportation.

Lay Person	Individual that does not have formal training in a specific field or discipline.
Traceability	Procedures and / or measures that enable the tracing of medical devices at any stage of the supply chain.
Intended Purpose	Means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.
Instruction for Use (IFU)	Means information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.
Contact Lens	Ophthalmic lens designed to be worn on the front surface of the eye.
Correction Lens	Contact lens intended to improve vision.
Cosmetic Lens	Contact lens specifically designed to change or mask the appearance of the eye. Note: Cosmetic contact lenses may be used for therapeutic purposes.
Soft Contact Lens	Contact lens made of a hydrogel material or non-hydrogel material which, in its hydrated final state and under normal conditions, contains a known water content, is easily deformable and may not retain its form without support.
Rigid Contact Lens	Contact lens made of non-hydrogel rigid materials that can flex slightly but do not substantially conforms to the shape of the cornea when on the eye.
Water Content	amount of water present in a hydrated contact lens under specified conditions of temperature, pH and osmolality.
Contact Lens Solution	A solution designed to be used for cleaning, disinfecting, rinsing, and/or storing contact lens.
Schedule for Wear/ In Use Period	Specified period of time from first use to when the product should be discarded
Wearing Modality	Contact lenses can be daily wear or extended wear.
Planned Replacement	contact lens for which the manufacturer has recommended a replacement period

Annex (2): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1.0 26/1/2020	– Changing from "Guidance on Content of Labeling of Soft Contact Lenses and Contact Lenses Solutions (MDS-G40)" to "Guidance on Content of Labeling of Contact Lenses and its Solutions (MDS-G14)" – Expanding the scope document to include all types of lenses instead soft contact lenses only. – Updating the checklist. – Removing the requirement related to the name/address of EU AR. – Updating the EPs. – Updating the "Annex (1): Definitions & Abbreviations"
1.0 26/1/2020	– Linguistic revisions. – Removing of the EU information as it relates to MDMA requirements, while this a guidance for labeling content. – Moving the sections related to translation into Arabic to separate sections with clarifications.